



16/02

PATENT
Attorney Docket No. 401730/SKYE PHARMA

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

AWADHESH K. MISHRA

Application No. 09/321,766

Art Unit: 1617

Filed: May 28, 1999

Examiner: E. J. Webman

For: THERMOPROTECTED
COMPOSITIONS AND PROCESS FOR
TERMINAL STEAM STERILIZATION
OF MICROPARTICLE
PREPARATIONS

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02 FC:102
03 FC:103

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396.00 OP

RESPONSE

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In response to the Office Action dated January 8, 2002, please enter the following amendments and consider the following remarks. Pages showing the requested changes are attached. This response is filed timely as it is accompanied by a petition and a fee for a two-month extension for filing a response under 37 C.F.R. § 1.136(a).

AMENDMENTS

IN THE SPECIFICATION:

Replace the paragraph beginning at page 3, line 8 with:

The "thermoprotecting agents" and "thermoprotecting conditions" are characterized by their ability to restrict the increase in volume weighted mean diameter of the particulate suspension during and after terminal steam sterilization to a limit that the steam sterilized suspension can be injected by intravenous or other parenteral routes of administration without compromising the safety of the subject. A volume weighted mean diameter of up to about 3 μm is considered safe for intravenous injection. However, such a suspension should not contain more than 3000 particles of 10 μm or greater size and not more than 300 particles of 25 μm or greater size according to the USP particulate test criterion. We have thus defined the term "successful steam sterilization" as a process with which one can prepare